REMARKS

Claims 24-27, 41-42, 49 and 57-62 are under examination and have been rejected. Applicants have canceled claim 62 and added new claims 67 and 68. Claims 24, 25, 49, 57 and 59 have been amended,

Co-Pending Applications

The Examiner has requested that Applicants note other co-pending applications in this line of cases.

Applicants respond that there are 5 co-pending applications, each of which is a continuation of the original parent application that matured into U.S. Patent 6,617,122. These 5 applications are Serial No. 10/744,465 (filed 23 December 2003), 10/833,679 (filed 28 April 2004), 10/818,279 (filed 5 April 2004), 10/617,334 (filed 10 July 2003 – the present case), and 10/452,510 (filed 2 June 2003). The status of these is:

1. Serial No. 10/833,679 (filed 28 April 2004) is recited in the Office Action (page 17, line 7 from bottom); a Terminal Disclaimer was filed.

2. Serial No. 10/617,334 (filed 10 July 2003) is the present case.

3. Serial No. 10/744,465 (filed 23 December 2003) contains claims 1-35 drawn to a method of screening for ABC1 modulators using gene modulation and claims 36-45 (withdrawn) directed to treating diseases or disorders by administering an agent that modulates ABC1 activity wherein the agent was identified using one of the gene modulation assays claimed therein. In the event that it is needed, Applicants submit herewith a Terminal Disclaimer for this application.

4. Serial No. 10/818,279 (filed 5 April 2004) contains only claims drawn to determining risk of cardiovascular disease in a patient by determining presence of a mutation or polymorphism in a protein or polynucleotide present in said patient and does not contain any treatment claims.

5. Serial No. 10/452,510 (filed 2 June 2003) contains claims drawn to substantially pure ABC1 polypeptides, polynucleotides, vectors and recombinant cells.

Information Disclosure Statement

In reviewing the prosecution file for this case, Applicants note that in the Office Action dated 31 May 2006, the Examiner, at page 4 thereof, notes that all of the references submitted in the IDS of 3/3/06 have been considered by the Examiner (these references were also considered in the parent patent) and that a copy of the Forms 1449 is attached to said Office Action. However, Applicants note that the only paper that was so attached was a Notice of References Cited by the Examiner and no copies of initialed Forms 1449 were attached. In addition, these also do not appear with the Office Action on PAIR and Applicants' file for this case does not appear to contain these forms as part of any other Office Action. Applicants respectfully request that the Examiner provides these with the next Office Action.

In addition, Applicants enclose herewith an additional IDS containing references cited by the EPO in a co-pending foreign case (along with a copy of the EPO Search Report).

Claim Objection

The Examiner has indicated potential objection to claim 62 as being duplicative of

claim 61. In an effort to advance prosecution, Applicants have canceled claim 62.

Rejection Under 35 U.S.C. §112, ¶2

Claims 24-27, 49 and 57-66 were rejected under 35 U.S.C. §112, ¶2, as being indefinite for failure to recite an active method step to achieve the claimed treatment but, instead, only reciting how the treatment is to be effected.

As noted in a previous amendment, clinical studies showed that plasma HDL-C concentration was inversely related to diseases like coronary artery disease (CAD) so that an increase in HDL is useful in treating diseases like those of the cardiovascular system. In response to this ground of rejection, Applicants have amended claim 24 (and thereby all pending dependent claims) to recite that an ABC1 increasing agent is administered whereby the increase is in the cells of the patient. Applicants have also added new claims 67 and 68, reciting that the cells are fibroblasts. Support for this claim language is found throughout the application, especially at page 4, lines 1-4 (low HDL-mediated efflux of lipids in Tangier Disease), at page 17, lines 6-10 (cholesterol efflux in subjects with Tangier Disease), at page 21, lines 10-31 (showing effects of anti-sense drugs on efflux from fibroblasts), at page 24, lines 3-5 (relation between ABC1 transcripts and cholesterol efflux in fibroblasts), at page 24, lines 8-12, and page 27, lines 6-7 (reciting cells with cholesterol trafficking, including fibroblasts), and at page 46, line 29, over to page 47, line 10 (assay for cholesterol efflux from human skin fibroblasts).

In accordance with amended claim 24, it may be necessary for the clinician to monitor ABC1 mediated efflux in cells, such as fibroblasts, from a patient to determine the appropriate level of the agent that achieves at least 10% increase in activity but such determination (given the assays provided in the application) are believed to be well within the skill of those in the art. Further, Applicants recite numerous agents that modulate ABC1 activity, including increasing said activity (see, for example, the application at page

53, lines 7-27).

Rejection Under 35 U.S.C. §101

Claims 24-27, 49 and 57-66 were rejected under 35 U.S.C. §101, as failing to recite a proper definition of a process. Applicants respond that the claim amendments recited above in response to the rejection for indefiniteness and the remarks thereon also avoid this ground of rejection.

Rejection Under 35 U.S.C. §112, ¶1

Claims 24-27, 49 and 57-62 were rejected under 35 U.S.C. §112, ¶1, as failing to meet the written description requirement on grounds that they contain subject matter not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention (i.e., a new matter rejection).

The Examiner contends *inter alia* that the claims do not recite what is actually treated by increasing ABC1 lipid transport activity (office action at page 6, lines 1-7) and that the claim is not limited to treatment by administering a compound (office action at page 10, lines 5-6). In response, Applicants have amended claim 24 (and thus all of the dependent claims) to recite that the claimed method is specifically drawn to increasing HDL levels in a patient by increasing ABC1 activity and is thus far more particular in reciting the condition to be addressed. As Applicants have related in a previous paper, the link between HDL and cardiovascular disease was demonstrated in the application. In addition, the amended claims also recite that increased HDL is achieved by administering an agent that increases ABC1 lipid transport activity. As noted previously, the reference in

the application to modulating ABC1 activity and HDL levels is intended to be alternative designations and not as different processes that can be separately modulated.

The claims have also been rejected on the basis of insufficient enablement (see office action at pages 9-14). In response, Applicants have amended the claims to better identify the contemplated invention (e.g., clearly reciting that ABC1 transporter activity is to be increased in amended claim 24 as the basis for increasing HDL levels by administration of agents, many of which are recited in the specification (see above citations to the application). In addition, Applicants have disclosed agents useful in increasing ABC1 lipid transport activity (e.g., ABC1 polypeptides and fragments in the previous response and other agents cited hereinabove).

Further, the Examiner notes the absence of working examples to support a claim to increasing ABC1 activity in a patient (see Office Action at page 13). In response, Applicants note that working examples are not essential to show enablement of a claimed invention. Instead, Applicants have provided examples of the effects of reduced ABC1 activity in patients and the concomitant effects on HDL (see the citations to the specification above) and have disclosed agents that increase ABC1 activity. Unless such link cannot possibly be maintained, Applicants contend that the link between ABC1 activity in cells, such as fibroblasts, of a patient and HDL levels has been shown and that increase in ABC1 activity should have the expected effect on HDL levels. In addition, Applicants disclose compounds that increase ABC1 activity.

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Respectfully submitted,

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